EXHIBIT H

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Attorneys for Defendant AGA MEDICAL CORPORATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MEDTRONIC, INC., a Minnesota corporation, MEDTRONIC USA, INC., a Minnesota corporation, and MEDTRONIC VASCULAR, INC., a Delaware corporation,

Plaintiffs,

v.

AGA MEDICAL CORPORATION, a Minnesota corporation,

Defendant.

Case No. 3:07-cv-00567-MMC (EMC)

DECLARATION OF CHARLES E. MULLINS, M.D. IN SUPPORT OF AGA'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NONINFRINGEMENT

U of M v. AGA
Dr. Charles Mullins
Depo. Ex. 42

I, Charles E. Mullins, declare as follows:

1. I am a physician, and my qualifications in the field of pediatric cardiology are set forth in my curriculum vitae, which is attached hereto as Exhibit A.

2. I understand that Medtronic alleges that the following AGA Accused Products infringe certain claims of U.S. Patent Nos. 5,067,957 ("the '957 patent"), 5,190,546 ("the '546 patent"), and 6,306,141 ("the '141 patent"): the AMPLATZER® Septal Occluder and Multi-Fenestrated Occluder, the AMPLATZER® Duct Occluder I and II, the AMPLATZER® PFO Occluder, the AMPLATZER® VSD Occluders (including the Membranous VSD Occluder, the Muscular VSD Occluder, and the P.I. Muscular VSD Occluder), the AMPLATZER® Vascular Plug, Vascular Plug II, and Vascular Plug III, and all delivery systems used in conjunction with each plug or occluder (collectively, the "Accused Products").

2. I also understand that the asserted claims of the '957 patent are all directed to methods of positioning or inserting medical devices within or proximate to bodies and that the one asserted claim of the '546 patent is directed to withdrawing a medical device from a body. I understand that the asserted claims of the '141 patent all are directed to medical devices.

3. AGA is not licensed to practice medicine and does not perform any medical treatments and does not insert or implant any of the Accused Products into a patient. Nor does AGA remove the Accused Products from patients.

4. Once an AGA device is detached from the delivery cable/wire, it is not designed to be removed from the body. If, after the AGA device is released and it must be removed, removal is completed through much more difficult procedures such as using a gooseneck snare to attempt to capture the attachment pin on the moving device, or through open heart surgery. The AGA devices rarely need to be recaptured and removed from the body in this way.

5. Physicians very rarely withdraw the Accused Products from patients, and withdrawal likely occurs in less than 2-5% of the cases implanted in the hands of competent interventionalists.

6. Physicians have sole responsibility for exactly how a medical device is used in patients. After approved medical training, physicians become licensed to "practice medicine."

Usually subsequent training and then further certification and credentialing by individual states and institutions are necessary before physicians are allowed to perform very specialized procedures. The physicians are the only ones given this authority for the use of medicines, procedures, or devices in human patients. Not even the FDA can "control" how devices or medicines are used in humans once they are "approved for human use."

7. AGA generates "Instructions for Use" or "IFUs" for each of its products. In some cases, the IFUs are different for each country. This can be because a device is approved for different uses in different countries. The IFUs are merely recommendations by the manufacturer of its opinion for the optimal use of the product, but the IFUs do not in any way control how the devices are used. Furthermore, where Dr. Feinstein insists that the IFUs in the United States are provided directly to doctors, today, they are only made available online for access if a physician chooses.

8. It is my opinion that the training that AGA provides physicians is one of the best in the industry. The training provides detailed instructions based on the IFUs, but no matter how detailed they might be, they are not "rules" nor are there any imposed penalties for not following those instructions.

9. It is my opinion that there is evidence showing widespread "off-label use" of the devices. Off-label use occurs when a physician treats a patient with a device in a method or intention not approved by an administrative body such as the FDA. I am aware of widespread "off-label use" of the AGA devices, and have engaged in off-label use of some AGA devices myself in order to treat unique patients more appropriately.

10. I am aware of a number of ways that the Amplatzer® devices are used off-label. Among those uses are using a septal occluder in a PDA, using a duct occluder to occlude an AV fistula, using a duct occluder to close a coronary fistula, closing a variety of fenestrations, and any use of the devices in the United States to fix a PFO.

11. Doctors also often choose different delivery sheaths than recommended in the IFUs. The size of delivery sheath in the IFU is a minimum size. However, in practice, a physician will often use a larger size than what is recommended in the IFUs. For example, A 12 French (4 mm

internal diameter) sheath is recommended for the delivery of the Amplatzer 34 – 40 mm Septal Occluder, but many physicians will start with a 14 French delivery sheath for the larger sized devices. This same fact holds true for all of the ranges of devices for recommended sheath size, and the largest device of a range of sizes recommended for any specific sheath size is delivered much more comfortably (and safely) using the next larger sized sheath than those recommended in the IFUs.

12. Although AGA sells delivery systems that can be used with the devices, customers are not in any way required to purchase and use its delivery systems. Many doctors choose to use sheaths, balloons, guide wires, and other devices not provided by AGA. For example, I personally found the original Amplatzer® Delivery Sheaths unacceptably prone to kinking after my use of them, and abandoned those sheaths to substitute a different delivery sheath for all subsequent AGA device deliveries.

13. Physicians who use AGA's AMPLATZER® Septal Occluder and Multi-Fenestrated Occluder, the AMPLATZER® Duct Occluder I and II, the AMPLATZER® PFO Occluder, the AMPLATZER® VSD Occluders (including the Membranous VSD Occluder, the Muscular VSD Occluder, and the P.I. Muscular VSD Occluder) (collectively, the "Occluders") must choose an appropriate means of delivering the Occluders and create an assembly for delivery.

14. Similarly, physicians who use the AMPLATZER® Vascular Plug, Vascular Plug II, and Vascular Plug III (collectively, the "Vascular Plugs"), which are not sold with delivery sheaths or delivery cables, must select and purchase delivery catheters or delivery sheaths to deliver the Vascular Plugs.

I declare under penalty of perjury of the laws of the United States of America that the foregoing is true and correct. Executed on February 27, 2009 at Houston, Texas.

/s/ Charles E. Mullins

Charles E. Mullins

FILER'S ATTESTATION

Pursuant to General Order No. 45, Section X (B) regarding signatures, I, Michael S. Connor, attest that concurrence in the filing of this document has been obtained.

/s/ Michael S. Connor

Michael S. Connor

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service, are being served this 27th day of February 2009 with a copy of this document via the Court's CM/ECF system.

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By /s/ Michael S. Connor
MICHAEL S. CONNOR

Attorneys for Defendant
AGA MEDICAL CORPORATION

EXHIBIT A

CURRICULUM VITAE

Charles Edward Mullins, MD

TITLES:

Professor Emeritus of Pediatrics, Baylor College of Medicine

Director Emeritus of the Cardiac Catheterization Laboratories, Texas Children's Hospital

Consultant, Adult Congenital Heart Disease, Texas Heart Institute

BIRTHDATE AND PLACE:

January 15, 1932,
Washington, D.C.

EDUCATION AND TRAINING:

1954, A.B. cum laude,
Princeton University, Princeton, New Jersey

1958, MD with Distinction,
The George Washington University
School of Medicine, Washington, D.C.

1958-1959, General Rotating Internship,
Walter Reed General Hospital, Washington, D.C.

1959-1961, Residency in Pediatrics,
Walter Reed General Hospital, Washington, D.C.

1961-1962, Residency in Cardiology,
Walter Reed General Hospital, Washington, D.C.

1962-1963, Fellowship in Cardiology,
Walter Reed General Hospital, Washington, D.C.

ACADEMIC APPOINTMENTS:

Professor of Pediatrics,
Baylor College of Medicine, 1982-2006

Associate Professor of Pediatrics,
Baylor College of Medicine, 1974-1982

Assistant Professor of Pediatrics,
Baylor College of Medicine, 1969-1974